ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 14

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 06/24/2014	2. CONTRACT NO. (If any): EP-C-11-038
3. ORDER NO.: 0021	4. REQUISITION/REFERENCE NO.: See Schedule

5. ISSUING OFFICE (Address correspondence to):
CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

6. SHIP TO:
a. NAME OF CONSIGNEE: US Environmental Protection Agency
b. STREET ADDRESS: US EPA
4930 Old Page Road
Room #: E311G
c. CITY: Durham
d. STATE: NC
e. ZIP CODE: 27703

7. TO:
a. NAME OF CONTRACTOR: BATTELLE MEMORIAL INSTITUTE
b. COMPANY NAME:
c. STREET ADDRESS: 505 KING AVE
d. CITY: COLUMBUS
e. STATE: OH
f. ZIP CODE: 432012693

f. SHIP VIA:

8. TYPE OF ORDER
☐ a. PURCHASE
REFERENCE YOUR:
Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

☒ b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: See Schedule

10. REQUISITIONING OFFICE: CPOD

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT: Destination

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION	b. ACCEPTANCE			
Destination	Destination		30 Days After Award	

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number (b)(4) DUNS Number: Determination of the Persistence of Non-spore-forming Biological Threat Agents in the Environment TOPO: M. Worth Calfee Continued ...					

18. SHIPPING POINT:
19. GROSS SHIPPING WEIGHT:
20. INVOICE NO.:
17(h) TOTAL (Cont. pages): $261,235.00

21. MAIL INVOICE TO:
a. NAME: RTP Finance Center
b. STREET ADDRESS (or P.O. Box): US Environmental Protection Agency
RTP-Finance Center
Mail Drop D143-02
109 TW Alexander Drive
c. CITY: Durham
d. STATE: NC
e. ZIP CODE: 27711
17(i) GRAND TOTAL: $261,235.00

SEE BILLING INSTRUCTIONS ON REVERSE

22. UNITED STATES OF AMERICA BY (Signature): 06/24/2014 Camille W. Davis ELECTRONIC SIGNATURE

23. NAME (Typed): Camille W. Davis
TITLE: CONTRACTING/ORDERING OFFICER

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION NOT USABLE

OPTIONAL FORM 347 (Rev. 2/2012)
Prescribed by GSA/FAR 48 CFR 53.213(f)

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
06/24/2014	EP-C-11-038	0021

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Admin Office: CPOD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: NWD Cincinnati OH 45268 Period of Performance: 06/24/2014 to 06/24/2015					
0001	Determination of the Persistence of Non-spore-forming Biological Threat Agents in the Environment. Award Type: Cost-plus-fixed-fee Total Estimated Cost: $(b)(4) Fixed Fee: $(b)(4) Completion Form Requisition No: PR-ORD-14-00919, PR-ORD-14-01919 Accounting Info: 13-14-C-264B000-401F72XPC-2532-26A6A-1 4264BE034-001 BFY: 13 EFY: 14 Fund: C Budget Org: 264B000 Program (PRC): 401F72XPC Budget (BOC): 2532 Cost: 26A6A DCN - Line ID: 14264BE034-001 Funding Flag: Partial Funded: $150,000.00 Accounting Info: 14-15-C-264B000-401F72XPC-2532-26A6A-1 4264BE042-001 BFY: 14 EFY: 15 Fund: C Budget Org: 264B000 Program (PRC): 401F72XPC Budget (BOC): 2532 Cost: 26A6A DCN - Line ID: 14264BE042-001 Funding Flag: Partial Funded: $111,235.00				261,235.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) $261,235.00

PERFORMANCE WORK STATEMENT
STREAMS II
Task Order 0021, Battelle EP-C-11-038

TITLE: Determination of the Persistence of Non-Spore-Forming Biological Threat Agents in the Environment

Task Order Contracting Officer Representative (TOCOR)	Alternate Task Order Contracting Officer Representative (ATOCOR)
Name: M. Worth Calfee	**Name:** Erin Silvestri
Office: USEPA ORD/NHSRC/DCMD 109 TW Alexander Drive RTP, NC 27711	**Office:** USEPA ORD/NHSRC/TCAD 26 W. Martin Luther King Drive Cincinnati, OH 45268
Phone: 919-541-7600	**Phone:** 513-569-7619
Email: Calfee.Worth@epa.gov	**Email:** Silvestri.Erin@epa.gov

Period of Performance: June 24, 2014 through June 24, 2015

PURPOSE OF TASK ORDER

The purpose of this work is to determine the persistence, or viability over time, of biological threat agents in the environment. These data are necessary for development of scientifically-defensible, agent-specific remediation plans following a biological incident.

BACKGROUND

EPA is designated a coordinating Agency, under the National Response Framework, to prepare for, respond to, and recover from a threat to public health, welfare, or the environment caused by actual or potential oil and hazardous materials incidents. Hazardous materials include chemical, biological, and radiological substances, whether accidentally or intentionally released. EPA is also designated a support Agency to support the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) activities in agricultural emergency response. EPA is also a lead agency under Section 208 of the Food Safety Modernization Act (FSMA) and is tasked under the FSMA to develop model plans for protecting the nation's food and agricultural infrastructure in such a way to protect human health and the environment. To adequately prepare the EPA, and its responders, to any potential contamination incident involving select agents, it is imperative to first understand the contaminants persistence in the environment following the contamination incident. These data will help to inform response and recovery activities that follow the incident.

This Performance Work Statement (PWS) describes the requirements for addressing an identified gap related to understanding biological threat agent survival on environmental substrates (surfaces and soil). This gap was identified recently by the US EPA Homeland Security Research Program (HS RAP) during a tabletop exercise. Addressing this gap will enable EPA, and the entire response community, to more effectively respond to a contamination incident involving a biological threat agent, should one occur.

The work will involve: preparing stock solutions of several biological threat agents; inoculating replicate pieces of environmental surface materials (coupons) with the agent; subjecting the test (and control) coupons to prescribed environmental conditions for up to 24 weeks; and determining the fraction of agent surviving at numerous time points.

TASK DESCRIPTIONS

Task 1 Brief Survey of the Open Literature

The contractor shall identify, collect, evaluate, and summarize available articles, reports, and other pertinent information related to growth, handling, and lyophilization procedures for the select agents listed in Table 1. For each agent, the optimal procedure that enhances the survivability over time shall be identified and suggested for use in the subsequent persistence tests. Methods that permit the agent to remain lyophilized after inoculation onto test materials are preferred for use in subsequent testing (i.e., methods that prevent rehydration during inoculation). These methods shall be agreed upon by the TOCOR and contractor, and included in the QAPP developed under Task 2 of this PWS.

Task 1 Deliverable: The literature review will be transmitted to the TOCOR in the form of a memo and an Excel file with the list of references, within 10 business days of award. No formal review or revision shall be necessary for this deliverable. The TOCOR shall review the deliverable, discuss the content of the articles with the contractor if necessary, and collectively give approval or disapproval for the test methods suggested by the contractor for use in Task 3.

Table 1. List of Select Agents and Strains to be used for Testing

Select Agent	Strain
Francisella tularensis	SchuS4
Yersinia pestis	CO92
Burkholderia mallei	China 7

Note: Up to three (3) Agents will be selected for inclusion in Task 3 (persistence testing).

Task 2 Development of a Quality Assurance Project Plan

The contractor shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)"attached to the PWS. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf or based on the type of research that is being conducted. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP must be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

Task 2 Deliverable: Draft QAPP to EPA 20 business days after TO award. EPA will review the Draft QAPP and provide comments back to Contractor within 10 business days. The revised QAPP will be submitted to EPA for final approval within 35 business days after TO award.

Task 3 Persistence Testing

The contractor shall, based upon the test design outlined in the QAPP, conduct a set of laboratory tests to evaluate agent survival over time. These tests systematically evaluate the matrix of test variables listed in Table 2. These tests shall be designed with adequate quality control measures, and conducted using methods consistent with previously-reported persistence studies (Calfee and Wendling, 2012, Sinclair et al., 2008, US Environmental Protection Agency, 2010, US Environmental Protection Agency, 2011, Cherwonogrodzky et al., 1994, Heckly and Blank, 1980, Ohtake et al., 2011, Bearden and Perry, 2005). Two (2) environmental substrates (sterilized glass and sterilized soil) shall be included in the study, and represent environments that may potentially harbor agent following a contamination incident. If recovery from soil is poor (< 0.1% of spike after zero days incubation), another common outdoor material may be substituted. Small-scale (i.e., 1.7 ml open-top tubes with small glass carrier or ~100mg soil) test samples may be used to increase feasibility (and reduce footprint required) of testing. Recovery methods shall be demonstrated for any new procedures prior to initiation of testing. All tests shall be conducted in static test chambers with test (and blank) sample exposure indoor light. All replicates for all time points within a series for each agent/prep/material type/environmental condition combination shall be inoculated on the same day.

Task 3 Deliverable: All environmental monitoring data (time, temp, RH, etc.), bacterial growth data (OD, time, etc.), and recovery data (CFU plate^{-1}, extract volume, CFU ml^{-1}, CFU total, etc.) shall be provided in Excel files. All data shall be QC'd before final submission to the TOCOR. Final data submission shall occur within 10 business days of the end of testing, no more than nine (9) months after award. The results of the QC findings shall also be included in this document. Preliminary data shall be sent to the TOCOR as they become available.

Table 2. Matrix of Persistence Testing Variables

Select Agent	Prep	Environmental Conditions	Material Types	Sample Types and Replicates	Time Points
Ft	Wet (PBS) Inoculum	Cold (5±3°C, 30±15 %RH)	Glass	5 Test, 1 Blank	1 zero, and at least 5 non-zero time points. Test duration = 100 days where necessary (testing continues if viable agent recovered, up to 100 days)
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		
	Lyophilized	Cold (5±3°C, 30±15 %RH)	Glass		
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		
Yp	Wet (PBS) Inoculum	Cold (5±3°C, 30±15 %RH)	Glass		
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		

	Lyophilized	Cold (5±3°C, 30±15 %RH)	Glass		
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		
Bm	Wet (PBS) Inoculum	Cold (5±3°C, 30±15 %RH)	Glass		
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		
	Lyophilized	Cold (5±3°C, 30±15 %RH)	Glass		
			Soil		
		Room (22±3°C, 40±15 %RH)	Glass		
			Soil		
		Warm (35±3°C, 65±15 %RH)	Glass		
			Soil		

Task 4 Report

A draft final report detailing the test methods and results shall be submitted to the EPA TOCOR within 20 business days following the completion of the testing and no later 10 months after the TO award date. The report shall include any digital photos, tables, and figures necessary to illustrate the findings. The EPA TOCOR will review the document and will provide comments within 10 Business Days. A final report incorporating requested changes, correction, and clarification resulting from the review process shall be submitted by the contractor within 15 days from receiving the official comments from the EPA TOCOR. A separate document detailing the response to comments shall also be submitted to the EPA TOCOR by the contractor with the final version of the report. The final report shall be provided within 12 months after the TO award date.

SCHEDULE

Table 3. Schedule of Deliverables and Due Dates

Task	***Deliverable***	***Schedule***
1	Summary of Brief Literature Survey	10 business days after award
2	QAPP - Draft	20 business days after award
2	QAPP - Final	35 business days after award
3	Final QC'd Data Summary and Summary of QC results	9 months after award
4	Detailed EPA-Style Report - Draft	10 months after award
4	Detailed EPA-Style Report - Final	12 months after award

SEVERABILITY

Task 3 is severable by agent, and may be incrementally funded. Proposals should include cost options for completing one, two, or three of the select agents under Task 3. Tasks 1, 2, and 4 are required regardless of the number of agents included under Task 3.

REFERENCES

BEARDEN, S. W. & PERRY, R. D. 2005. Laboratory Maintenance and Characterization of Yersinia pestis. *Current Protocols in Microbiology.* John Wiley & Sons, Inc.

CALFEE, M. W. & WENDLING, M. 2012. The effects of environmental conditions on persistence and inactivation of *Brucella suis* on building material surfaces. *Letters in Applied Microbiology,* 54, 504-10.

CHERWONOGRODZKY, J. W., KNODEL, M. H. & SPENCE, M. R. 1994. Increased encapsulation and virulence of Francisella tularensis live vaccine strain (LVS) by subculturing on synthetic medium. *Vaccine,* 12, 773-5.

HECKLY, R. J. & BLANK, H. 1980. Virulence and viability of Yersinia pestis 25 years after lyophilization. *Applied and Environmental Microbiology,* 39, 541-543.

OHTAKE, S., MARTIN, R. A., SAXENA, A., LECHUGA-BALLESTEROS, D., SANTIAGO, A. E., BARRY, E. M. & TRUONG-LE, V. 2011. Formulation and stabilization of Francisella tularensis Live Vaccine Strain. *Journal of Pharmaceutical Sciences,* 100, 3076-3087.

SINCLAIR, R., BOONE, S. A., GREENBERG, D., KEIM, P. & GERBA, C. P. 2008. Persistence of Category A Select Agents in the Environment. *Appl. Environ. Microbiol.,* 74, 555-563.

US ENVIRONMENTAL PROTECTION AGENCY. 2010. *Persistence Testing of Brucella suis on Outdoor Materials* RTP, NC. Report No. EPA/600/R-10/026.

US ENVIRONMENTAL PROTECTION AGENCY. 2011. *Persistence and Decontamination Testing of Brucella suis*. Research Triangle Park, NC: US EPA. Report No. EPA 6000/R-11/111.

ATTACHMENT

NHSRC Quality Assurance Requirement Forms

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	Determination of the persistence of non-spore-forming biological threat agents in the environment
Description:	Laboratory Study to determine persistence of select agents over time on environmental substrates
Project ID:	HS4.03.01
Status:	Original
Number Ammended:	
QA Category:	III
Action Type:	Extramural
Peer Review Category:	III
Security Classification:	Unclassified
Project Type:	Sampling and Analysis
QAPP Status 1:	Not Delivered
QAPP Status 2:	Not Applicable
QAPP Status 3:	Not Applicable
Vehicle Status:	New Vehicle
Vehicle Type:	Contract

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes — Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes — Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?
(If "No" then skip to Section IV, and sign the form.)

No — Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

No — Has a QAPP already been approved for the activities specified in the SOW?

No — Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? (QA approval must be obtained before the contractor can start work.)

QAPP to be prepared after contract award

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

Before Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Other	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract. Developed in accordance with:
	Explain: NHSRC QMP
	Programmatic QA Project Plan developed in accordance with:
Other	Application of QA and QC activities to the single project covered by contract. QA Project Plan developed in accordance with:
	Explain: NHSRC QMP

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
Other	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with:
	Explain: The QAPP shall be deveoped in accordance with NHSRC QMP and attachment #1
NHSRC QMP	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

Worth Calfee NHSRC-DCMD Technical Lead Person	02/05/2014 Date	Eletha Roberts NHSRC-IO QA Staff Member	Ramona Thomas 02/07/2014 Date

QAPP REQUIREMENTS FOR SAMPLING AND ANALYSIS PROJECTS
(from Appendix B of the NHSRC QMP)

A sampling and analysis activity or project is typically defined as a study performed to generate data to either monitor parameters on a routine basis or to characterize a particular population for later studies. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT DESCRIPTION AND ORGANIZATION

1.1 The purpose of the study shall be clearly stated in the sampling and analysis plan (SAP).

1.2 Responsibilities and points of contact for each organization shall be identified in the SAP. This should include identification of key personnel and/or organization(s) responsible for sample collection and custody, analytical and/or process measurements, data reduction, report preparation, and quality assurance.

SECTION 2.0, SAMPLING

2.1 Sampling points for all measurements (*i.e.*, analytical, physical, and process, including locations and access points) shall be identified in the SAP whenever possible. If the specific locations cannot be identified at the time of plan generation, discuss the documentation and/or communication mechanism(s) for ensuring adequate information is captured to later identify sampling points.

2.2 The anticipated sampling frequency (*e.g.*, how many sampling events and how often events occur) and number of sample types (*e.g.*, metals, VOCs, SVOCs, *etc.*) taken at each event shall be provided.

2.3 The expected measurements (*i.e.*, specific analytes) planned for each sample type shall be summarized.

2.4 If applicable, known site_specific factors that may affect sampling procedures shall be described.

2.5 If applicable, any site preparation (*e.g.*, sampling device installation, sampling port modifications) needed prior to sampling shall be described.

2.6 Each sampling procedure to be used shall be discussed or referenced.

2.7 If compositing or splitting of samples is planned, the applicable procedures shall be described.

2.8 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

2.9 Containers used for sample collection, transport, and storage for each sample type shall be described.

2.10 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*) shall be described.

2.11 Requirements for shipping samples shall be described.

2.12 Holding times requirements shall be noted.

2.13 Procedures for tracking samples in the laboratory and for maintaining chain_of_custody when samples are shipped shall be described. COC procedures shall be described to ensure that sample integrity is maintained (labeling, seals, records).

2.14 Information to be recorded and maintained by field personnel shall be discussed.

SECTION 3.0, TESTING AND MEASUREMENT PROTOCOLS

3.1 Each analytical method to be used shall be referenced. This includes EPA-approved and other validated nonstandard methods.

3.2 If applicable, modifications to EPA_approved or other validated nonstandard methods shall also be described.

SECTION 4.0, QA/QC CHECKS

4.1 The SAP shall list and define all QC checks and/or procedures used for the project, both field and laboratory as needed.

4.2 For each specified QC check or procedure, required frequencies and acceptance criteria shall be included.

SECTION 5.0, DATA REDUCTION AND REPORTING

5.1 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

5.2 The reporting requirements (*e.g.*, units, reporting method [*e.g.*, wet or dry]) for each measurement and matrix shall be identified.

SECTION 6.0, REPORTING REQUIREMENTS

The deliverables expected from each organization responsible for field and/or analytical activities shall be described.

Attachment # 2

NHSRC QA
To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) **a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;**
(2) **an organizational chart showing the position of the QA function;**
(3) **delineation of the authority and responsibilities of the QA function;**
(4) **the background and experience of the QA personnel who will be assigned to the project; and**
(5) **the organization's general approach for accomplishing the QA specifications in the SOW.**

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to

ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces

for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)
STREAMS II
Task Order 0021, Battelle EP-C-11-038

TITLE – Determination of the Persistence of Non-Spore-Forming Biological Threat Agents in the Environment

TASK ORDER MANAGER – M. Worth Calfee

Performance Objective (Task)	Performance Standard (PS)	Surveillance Plan (SP)	Contractor Incentive (CI)	✓ or X
Task 1 Literature Review	Contractor provides results of brief literature survey within 10 business days after TO award	TO-COR will document whether receipt of deliverable is timely. TO-COR will document whether quality of deliverable is at an acceptable level.	TO-COR will address compliance in PPE	X
Task 2 Development of a Quality Assurance Project Plan	Contractor provides draft QAPP within 10 days after EPA approval of selected methods under Task 1	TO-COR will document whether receipt of deliverable is timely. TO-COR will document whether quality of deliverable is at an acceptable level.	TO-COR will address compliance in PPE	X
Task 3 Persistence Testing	Contractor provides preliminary data as they become available. Contractor shall QC final data, provide final data summary file and documentation of QC results. Final results and QC files shall be provided within 9 months after TO award.	TO-COR will document whether receipt of deliverable is timely. TO-COR will document whether quality of deliverable is at an acceptable level.	TO-COR will address compliance in PPE	X
Task 4 Report	Contractor provides a draft report detailing methods and results, 10 months after TO award. The contractor shall address EPA comments and provide a final version of the report within an additional 15 days after receipt of EPA comments, and within 12 months after TO award.	TO-COR will document whether receipt of deliverable is timely. TO-COR will document whether quality of deliverable is at an acceptable level.	TO-COR will address compliance in PPE	X